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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,180	02/12/2004	Marc Beauregard	15943-2US MG/dp	3080
7590 07/28/2005			EXAMINER	
Marc Beauregard's 2870 Bourjoly Trois-Rivieres, QC G8Z 2A9 CANADA .			LIU, SUE XU	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/776,180	Applicant(s) BEAUREGARD ET AL.	
	Examiner Sue Liu	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, drawn to a method of inducing random mutations in a nucleic acid sequence comprising the steps of providing a DNA template to polymerization reaction, classified variously, for example in class 435, subclass 91.1.
 - II. Claims 11-13, drawn to a method of preparing a library of mutated recombinant nucleic acid sequence, classified variously, for example in class 435, subclass 91.4.
 - III. Claim 14, drawn to a method of preparing a library of expression library and expressing protein analogs, classified variously, for example in class 435, subclass 69.1.
 - IV. Claim 15, drawn to use of an alcohol, classified variously, for example in class 435, subclass 441.
 - V. Claim 16, drawn to a composition of DNA polymerase and alcohol, classified variously, for example in class 435, subclass 91.2.
 - VI. Claim 17, drawn to a method of inducing mutations in a DNA fragment, classified variously, for example in class 435, subclass 91.4.

The inventions are distinct, each from the other because of the following reasons:

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2. Inventions of Groups I-III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions in Groups I-III and VI direct to various distinct methods, because they use different steps, require different reagents and/or will produce different results. The invention of Group I directs to a method of DNA polymerization, and requires the step of “to destabilize said DNA polymerase,” and the reagent of “a mesophile polymerase”, which are step and/or reagent that are not required by any of the Groups II, III and VI. Group II method requires the step of “to lower the fidelity of said DNA polymerase” and the reagent of “protein analogs”, which are step and/or reagent that are not required by other groups (I, III, and VI). Group III directs to a method of expressing proteins, and requires steps and/or reagents such as “a promoter” that are not recited in other groups (I, II and VI). Group VI recites a method of adding alcohol in a polymerization reaction, which could produce different products/results (such as labeled DNA probes) from other groups (I-III). Thus, inventions of Groups I-III and VI are distinct, and restriction between the groups is proper.

3. Inventions of Groups V and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Group V invention drawn to a composition of DNA polymerase and alcohol, which can be used in a materially different process from polymerase chain reaction. For example, the composition of Group V can be used to extend nicked DNA

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fragments or to label DNA probes with sticky ends. Thus, restriction between the groups is proper.

4. Inventions of Group V and Groups (II, III, & VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case, the different methods described in Groups II, III, and VI use different compositions from the one recited in Group V. For examples, protein analogs are required in Group II; a library expression vector is required in Group III; a DNA template is required in Group VI. Group V composition does not recite these requirements, and thus restriction is proper.

5. Invention of Group IV and Groups (I-III, V and VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Group IV directs either to a method of using alcohol or a composition, and could either require different steps/reagents or have different structures/functions from that of the other Groups (I-III, V and VI). For example, alcohol can be used in a materially different process such as an organic chemical synthesis method. Thus, restriction between the groups is proper.

6. Therefore, these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. The different methods and products will require

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completely different searches in both the patent and non-patent databases, and there is no expectation that the searches will be coextensive. Therefore, these do create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

7. This application contains claims directed to the following 5 sets of patentably distinct species of the claimed invention. Applicants are requested to further elect a single ultimate species for each of the following:

A.) A single ultimate species of DNA polymerase selected from the categories of thermostable, mesophile, Type A OR Type B polymerase. Applicants are further requested to select a single specific species of DNA polymerase within each categories of polymerase elected from the species of *Thermus aquaticus*, *Thermococcus litoralis*, *Pyrococcus* species GB-D, *Bacillus stearothermophilus*, *Pyrococcus furiosus*, Bacteriophage T7 (type A), Bacteriophage T7 (Type B), *Thermus thermophilus*, OR *Pyrococcus woesei*.

B.) A single range of alcohol concentration as defined by the molar concentration in a reaction.

C.) A single specific species of alcohol selected from propanol, ethanol, 2-aminoethanol, 1-propanol, 2-propanol, 1,2-propanediol, 1,3-propanediol, propanethiol, 1-butanol, 2-butanol, OR tert-butanol.

D.) A single specific type of nucleotide mutation selected from a transversion, an insertion, a transition, OR a deletion.

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E.) A single specific and defined number of nucleotide mutations per nucleic acid sequence. (e.g. 4 mutations per nucleic acid sequence.)

The species are distinct, each from the other, because their structure and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purpose as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. No matter which group Applicants elect, Applicants should identify which claims they believe are generic for each of the corresponding species sets A.)-E.), and which claims read on a particular species within the species sets A.)-E.) For example, Applicants' reply might state "...claim X is generic to the elected species of species sets A.), C.) and E.), but reads on the particular elected species for species sets B.) and D.)" Should a given species not pertain to Applicants' elected group, Applicants should indicate

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accordingly. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

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are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the fPatent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sue Liu
Art Unit 1639
7/20/05


PADMASHRI PONNALURI
PRIMARY EXAMINER